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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,215	06/15/2001	Peter A. Crooks	50229-267	5136

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Washington, DC 20005-3096

EXAMINER

FAY, ZOHREH A

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/881,215	Applicant(s) PETER CROOKS	
	Examiner Zohreh Fay	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 9, 11 and 13-20 is/are pending in the application.
4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 5, 7, 9, 11 and 13-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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Claims 5, 7, 9, 11 and 13-20 are presented for examination.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 7, 9, 11 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wada et al. (1997).

Wada et al. Teach 1-(m-chlorophenyl)-biguanide and its therapeutic use in the treatment of seizure (i.e. reduction of occurrence) associated with epilepsy. See the abstract. Since 1-(m-chlorophenyl)-biguanide has the structure that is embraced by the generic formula agmatine analog required by claim 5, all the claimed subject matter is met by the teaching of cited reference and it is not patentably distinct over the prior art of record. Wada et al. Differs from the claimed invention in the specific dosage regimen (0.1-500 mg/kg) and using a human subject as it is required by claims 13-20. It would have been obvious to a person skilled in the art to use the information from an animal study and incorporate it into human use, considering that animal studies are the

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preliminary steps for human study. The determination of optimum proportions or amounts is considered to be within the skill of the artisan in the absence of evidence to the contrary. One skilled in the art would have been motivated to employ the teachings of the above reference, since it relates to a compound within the scope of the claimed invention for the treatment of seizures associated with epilepsy. The determination of optimum proportions or amounts is considered to be within the skill of the art in the absence of evidence to the contrary. To use animal studies as a preliminary step for human studies is also within the skill of art.

Claims 5, 7, 9, 11 and 13-20 are rejected under 35 U.S.C. 103 as being unpatentable over Uzbay (2000) in view of Rajasekaran (2000).

Uzbay teaches the use of agmatine (40mg) for the treatment of audiogenic seizure due to ethanol withdrawal. See page 156. It further teaches that the therapeutic effects are resulted from blocking nitric oxide synthesis and selective inhibition of the NMD subclass of glutamate receptor channels. The above reference differs from the claimed invention in treating seizure caused by epilepsy and also the use of compound in human subject. Rajasekaran teaches the anticonvulsant activity of agmatine used in the treatment of seizure due to epilepsy. See pages 1-5.

Rajasekaran further teaches the underlying mechanism for anticonvulsant activity is utilizing NO inhibition, wherein NO is produced in the neurons in response to activation by NMD receptors, see page 1. Thus, it would have been obvious to a person skilled in the art to modify Uzbay's teaching in view of Rajaekaren to treat seizure caused by not only ethanol withdrawal but also due to epilepsy. It would have been obvious to a

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person skilled in the art to use a compound used for treating seizure and use for the treatment of seizure due to any cause in the absence of evidence to the contrary.

Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 5, 7, 9, 11 and 13-20 are properly rejected under 35 U.S.C. 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200

Zohreh Fay